

**PATENT**

**Attorney Docket No.: 36290-0449-00-US**

**IN THE UNITED STATES PATENT AND TRADEMARK OFFICE**

In re: Patent Application of	:	Group Art Unit: 1767
FRASER JAMES BUCHANAN	:	
Serial No: 10/589,037	:	Examiner:
	:	Angela C Scott
Filed: November 14, 2006	:	
For: BIOABSORBABLE	:	Conf. No. 4052
IMPLANTABLE STRUCTURE	:	

**DECLARATION OF PROFESSOR ARNE MILLER UNDER 37 C.F.R. 1.132**

Mail Stop RCE  
Commissioner for Patents  
P.O. Box 1450  
Alexandria, VA 22313-1450

I, Professor Arne Miller, declare as follows:

1.0 I have worked in the field of radiation processing, including radiation modification of materials for 41 years. I am currently a Professor at the Risø DTU, Technical University of Denmark, a position I have held for 3 years. My duties involve operating the accredited Risø High Dose Reference Laboratory and being Editor-in-Chief for the journal Radiation Physics and Chemistry (Elsevier). I am not directly employed by the Queen's University of Belfast and do not have any direct financial interest in the invention or the patent application. Risø High Dose Reference Laboratory has irradiated samples on behalf of the inventor, Fraser Buchanan. This work has been performed based on standard commercial terms.

2.0 I have read and understood US Patent Application 10/589037 and the claims as presently pending at the United States Patent and Trademark Office (USPTO). I have also read

- the Office Action issued by the USPTO on the above application dated 28 October 2011;
- Shalaby reference (US2004/0133237);
- Applicant's response to the examination report dated 11 March 2011;
- Advisory Action dated 23 March 2011.

3.1 From my understanding of the Shalaby reference, as acknowledged by the Examiner, I do not believe Shalaby teaches rotation of an absorbable medical device (suture) in an e-beam.

3.2 Further, from my understanding of the teaching of Shalaby, as Shalaby does not distinguish between the use of gamma radiation and electron beam radiation, nor provide any discussion of the energy of the electron beam which should be used, I believe a skilled person in the art would understand Shalaby to be concerned with the homogenous degradation of a polymer in a medical device.

3.3 Multisided irradiation or rotation of the device in front of the radiation beam is not mentioned by Shalaby. Based on the absence of any such a teaching, in order for the device to be sterilized, penetrating radiation must therefore be used.

3.4 Further, based on the absence of any teaching of the energy and thus penetrance of the electron beam used in Shalaby, and the absence of any discussion to distinguish the effect of electron beam radiation and gamma radiation, I believe the skilled person would understand an electron beam should be used in the method of Shalaby which would fully penetrate the medical device. This would be in accordance with conventional techniques used to sterilise medical devices such as sutures using an e-beam, and is as suggested by the examples which relate to a suture and the use of gamma radiation. Additionally, Shalaby does not provide any teaching or suggestion which would suggest such conventional techniques would not be used.

3.5 Shalaby teaches that it is directed to a method of “modulating the physical properties of absorbable, ester-based polymer” (see paragraph [0005]). Persons skilled in the art would understand “modulating” to mean “changing”, and I find no mention of the generation of change gradients. I therefore understand “modulating” to mean modulation of homogeneous physical properties. Shalaby mentions “the mass loss breaking strength retention profiles”. A person skilled in the art would understand these profiles to be modulation as function of homogeneous dose.

3.6 Further, based on my understanding that the teaching of Shalaby is concerned with modulating the breaking strength of a medical device such as a suture, to allow an assessment of breaking strength to be made more easily, it would appear that a uniform degradation of the polymer across the thickness of the medical device would be sought. This contrasts the claimed molecular weight distribution of the present invention which changes gradually from the outer surface to the core wherein the average molecular weight at the core is greater than the entire outer surface.

3.7 Where Shalaby discusses the use of the dose modulation using high energy radiation to shorten the time frame required for absorbable devices to undergo practically complete adsorption at the implant site (paragraph [0010] of Shalaby), there is again no discussion or suggestion provided by Shalaby of different molecular weight distribution across the thickness of the device. Thus, this appears to emphasise that Shalaby is concerned with a uniform degradation of the polymer across the thickness of the medical device.

3.8 Thus, in my opinion, one of ordinary skill in the art would not consider Shalaby to provide any teaching or suggestion of the claimed subject matter of the present application of an implantable substrate with an outer surface and a core wherein the molecular weight distribution changes gradually from the outer surface to the core such that average molecular weight at the core is greater than at the entire outer surface.

3.9 Further, based on my understanding of the teaching of Shalaby, I do not consider a person of skill in the art would expect the method for sterilising and modulating the physical properties of a medical device of Shalaby to result in an implantable substrate as claimed wherein the implantable substrate has a molecular weight distribution that changes gradually from the outer surface to the core such that average molecular weight at the core is greater than at the entire outer surface and that results in the rate of bioabsorbability of the core of the device being less than the rate of bioabsorbability of the surface of the device.

I hereby declare that all statements made herein of our own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

2011.04.26  
(date)

AM  
Professor Arne Miller

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